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EU mHealth label for a single market that enables
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authorities to benefit from a healthy supply of useful apps
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## **D4.1 Article patient citizen carer survey**

European residents' use and trust of health app recommendations and perceived need for review and rating by governments: Survey

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Partner(s) contributing: EPF, EuroHealthNet

#### Author(s):

Mariam Shokralla LUMC
Romy Willemsen LUMC
Petra Hoogendoorn LUMC



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#### **Abstract**

This study aimed to explore whose recommendations about health apps European residents use and trust and if they think the government should rate and review health apps to help them choose. An explorative quantitative study, using a tailored digital survey (Castor Electronic Data Capture), was conducted. The survey was completed by 1228 respondents from 33 European countries. While the recommendations for health apps from health professionals (80.4%) and pharmacists (61.1%) were most trusted, this did not yet reflect in their use (33.6% and 7.9%). In total 86.3% of the respondents thought that the government should review and rate health app quality or pay another organization to do so. Recommendations for health apps from trusted sources were underutilized, while untrusted sources were used, signalling a need for trusted information in untrusted sources and support measures to promote recommendations by trusted sources (health professionals, pharmacists).

#### Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Views and opinions expressed are those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.

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#### **EXECUTIVE SUMMARY**

There is a growing recognition of the role health apps can play in addressing health system challenges. Over 350,000 health apps are currently available in app stores. Yet, their quality and the robustness of the underlying scientific evidence are known to differ significantly. However, app stores provide near to no decision support, making it difficult for people to choose the right app for them. Trusted recommendations and health app assessments may help address this situation. Yet research about whose advice for health apps European residents use and trust and if they think health apps should be reviewed and rated lacks.

This study aimed to explore whose recommendations about health apps European residents use and trust and if they think the government should rate and review health apps to help them choose.

An explorative quantitative study, using a tailored digital survey (Castor Electronic Data Capture), was made available via the project website (www.label2enable.eu) from December 7, 2022, to February 16, 2023. The survey targeted residents from the European Economic Area, the United Kingdom and Ukraine. The survey was created in lay language and made available in 26 languages to also enable the participation of residents with low literacy. Recruitment was pursued primarily via the social media channels of the project, project partners and related organizations, and individuals related to the project.

The survey was completed by 1228 respondents from 33 European countries. The respondents' mean age was 47 years. Most were female (64.1%), had a bachelor's degree or more (81.5%), were in good or very good health (69.7%) and did not provide informal care (74.1%). In total 90.4% used one or more health apps. COVID-19 (62.1%) and activity apps (60.0%) were the most used, and disease management (7.0%), diagnostic (6.3%) and treatment (5.7%) apps were the least used apps. While the recommendations for health apps from health professionals (80.4%) and pharmacists (61.1%) were most trusted, this was not reflected in their use (33.6% and 7.9%). Conversely, although recommendations of family and friends (41.7%), app stores (11.7%) and Google searches (9.6%) were trusted less, they were relatively often used (35.3%, 23.7% and 23.0%). In total 86.3% of the respondents thought that the government should review and rate health app quality or pay another organization to do so, to help them choose health apps.

Our survey results showed that 86.3% of European residents thought their government (health authority) should rate and review health apps or commission a third-party to do so, urging governments to pursue such efforts to help address the challenges their health systems face. Recommendations for health apps from trusted sources were underutilized, while untrusted sources were used, signaling a need for trusted information in untrusted sources and support measures to promote recommendations by trusted sources (health professionals, pharmacists).

## 1 Introduction

Health systems in Europe are faced with an ageing population, increased burden of chronic disease, pressured health budgets, unequal quality and access to health care services and staff shortages<sup>1</sup>. There is a growing recognition that health and wellness apps (hereafter health apps) need to play a much stronger role in health care provision, self-care, and health prevention than they do today<sup>2,3</sup>. Over the past decade, the number of available health apps heavily increased, leading up to 350,000 available health apps in app stores in 2020<sup>4</sup>. Despite the need for and availability of health apps, the uptake by consumers and health professionals lags behind<sup>5</sup>. Moreover, use is skewed towards younger, and higher educated consumers, with higher levels of e-health literacy skills, from affluent or intermediate social and urban milieus<sup>6,7,8</sup>.

A considerable number of people are hesitant to download and use apps<sup>9</sup>. They currently lack the means to adequately understand how to assess the quality and reliability of the many apps in app stores, the commonplace to find health apps<sup>10,11</sup>. In the status quo, the only information available for consumers at the point of download is the app description and a star-based rating system based on user opinions that is not backed up with any systematic quality evaluation<sup>12</sup>. Yet app descriptions were found to not give sufficiently trustworthy information<sup>13</sup>, the starbased ratings a poor indication of clinical utility or usability<sup>14</sup> and quality and robustness of evidence to differ considerably<sup>15</sup>.

Trust is a critical factor in digital health adoption<sup>16</sup>. A recent Australian study highlighted consumers trusted recommendations from their General Practitioner (GP) most and from app stores and a Google search least<sup>17</sup>. However, Australian GPs reported not knowing which health apps are effective and lacking a source of trustworthy apps. As a result, they scarcely recommended health apps<sup>18</sup>. An experimental vignette study in Germany, the Netherlands and Spain showed that recommendations from a doctor increased the intention to download an app<sup>19</sup>. Nevertheless, In most European countries except Germany, there is no formal prescription or recommendation practice of health apps<sup>20,21</sup>. And French and German GPs, similar to Australian colleagues, report not feeling capable to give their patients expert advice on health apps. Their concerns include workload, data privacy and ease of use and safety for patients, and their needs for certification by an independent authority, transparency,

<sup>&</sup>lt;sup>1</sup> https://academic.oup.com/policyandsociety/article/42/1/14/6594422

<sup>&</sup>lt;sup>2</sup> https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf

<sup>&</sup>lt;sup>3</sup> https://pubmed.ncbi.nlm.nih.gov/28527495/

<sup>&</sup>lt;sup>4</sup> https://www.iqvia.com/newsroom/2021/07/consumer-health-apps-and-digital-health-tools-proliferate-improving-quality-and-health-outcomes-for

<sup>&</sup>lt;sup>5</sup> https://www.iqvia.com/newsroom/2021/07/consumer-health-apps-and-digital-health-tools-proliferate-improving-quality-and-health-outcomes-for

<sup>&</sup>lt;sup>6</sup> https://www.tandfonline.com/doi/full/10.1080/01972243.2018.1438550

<sup>&</sup>lt;sup>7</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5935808/

<sup>8</sup> https://europepmc.org/article/pmc/pmc9247815

<sup>9</sup> https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/1472-6947-13-23

<sup>10</sup> https://pubmed.ncbi.nlm.nih.gov/34267296/

<sup>11</sup> https://www.frontiersin.org/articles/10.3389/fdgth.2022.765993/full

<sup>12</sup> https://www.businessofapps.com/insights/reviews-ratings-affect-app-store-optimization/

<sup>13</sup> https://www.nature.com/articles/s41746-019-0093-1

<sup>14</sup> https://pubmed.ncbi.nlm.nih.gov/27920321/

<sup>15</sup> https://pubmed.ncbi.nlm.nih.gov/34910582/

<sup>&</sup>lt;sup>16</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6315261/

<sup>&</sup>lt;sup>17</sup>https://chf.org.au/sites/default/files/results\_of\_australias\_health\_panel\_survey\_on\_recommendations\_and\_regul ation\_of\_smartphone\_apps\_for\_health\_and\_wellness.pdf

<sup>18</sup> https://mhealth.jmir.org/2019/6/e13199/

<sup>&</sup>lt;sup>19</sup> https://mhealth.jmir.org/2020/6/e17272

<sup>&</sup>lt;sup>20</sup> https://www.researchprotocols.org/2022/4/e32702

<sup>&</sup>lt;sup>21</sup> https://mhealth.jmir.org/2023/1/e43561#ref2

prescription support and training programs<sup>22,23</sup> <sup>24</sup>. A vast majority of Australian consumers think the government should have a scheme where health apps are given a rating for accuracy and effectiveness (58.3%) or pay another organization to rate apps (31.0%)<sup>25</sup>. EU-wide research on whose recommendations for health apps residents use and trust and if they think the government should review and rate apps is lacking.

<sup>&</sup>lt;sup>22</sup> https://link.springer.com/article/10.1007/s10354-021-00814-0

<sup>&</sup>lt;sup>23</sup> https://mhealth.jmir.org/2022/2/e28372

<sup>&</sup>lt;sup>24</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7974757/

 $https://chf.org.au/sites/default/files/results\_of\_australias\_health\_panel\_survey\_on\_recommendations\_and\_regulation\_of\_smartphone\_apps\_for\_health\_and\_wellness.pdf$ 

## 2 Objectives

The primary objectives of this study were to explore:

- 1. whose recommendations European residents use to choose a health app
- 2. whose recommendations European residents trust to choose a health app
- 3. if European residents think the government should review and rate health apps to help them choose.

To ensure an adequate understanding among the respondents of what a health app is and be able to consider their answers in light of their level of experience with health apps, we will explore which health apps the respondents use(d).

The secondary objective of this study is to explore potential differences by sex, age and educational level with regard to used apps, used and trusted sources of advice about health apps.

## 3 Methods

## 3.1 Design and respondents

An 11-item digital survey (Appendix 1) using Castor Electronic Data Capture (Castor EDC) was open for response for 10 weeks, starting December 7, 2022, and ending February 16, 2023. This cross-sectional descriptive, exploratory study targeted residents of at least 18 years old currently residing in the European Economic Area, the United Kingdom and Ukraine, able to read and write and respond to a digital survey. There were no further inclusion or exclusion criteria.

There was no sample size calculation, because of the explorative and descriptive nature of the study. We aimed for a mixed representative population in country of residence, age, gender, educational level, health status and informal caregiver status. The response rates were monitored biweekly against these indicators, and the dissemination efforts were adjusted accordingly.

The survey was drafted in English and then translated by official translators into 25 other languages resulting in availability in the survey in 22 of the 24 official EU languages (excluding Irish and Maltese), Norwegian, Ukrainian, and Arabic and Turkish, the 2 most spoken immigrant languages in Europe<sup>26</sup>. Irish and Maltese were excluded since English is widely spoken in these countries. The translations were subsequently validated by native speakers with a background in digital health to ensure the accuracy of the terminology used. The language of the survey was intentionally kept simple to support the participation of people with low literacy.

Separate links per language were made available on the Label2Enable website (www.label2enable.eu) (Appendix 2). Respondents could click these general non-personal links for their language of choice to fill out the survey. The survey links were disseminated using the Label2Enable project social media channels and newsletter. A social media campaign with visuals and animated graphics interchange formats (GIFs) was made available to the project partners and related organizations, such as the European Patients' Forum (EPF), EuroHealthNet, Eurocarers, and the European Commission to assist in the dissemination.

No personal (identifying) information was collected, as such respondents remained anonymous. Due to the nature of the study, the need for ethical approval was waived by the Medical Ethics Committee of Leiden – Delft – Den Haag (22-3069 dd 14 Nov 2022).

#### 3.2 Outcome measures

The survey consisted of two sections. Section 1 contained 6 socio-demographic questions, covering country of residence, year of birth, gender, educational level, and self-reported health, and informal caregiver status. Section 2 contained 4 questions spanning used apps, used advice, trusted advice and thoughts on the government reviewing and rating apps. Moreover, an open text box was available to add potential final thoughts or comments. Respondents could indicate which apps they use(d) with a list of 17 multiple-choice options. For advice used to choose a health app, a list of 15 potential sources for advice was provided. For trusted advice, respondents could indicate their level of trust for the same list of potential sources for advice on a 4-point Likert scale ranging from 'I trust' to 'I am not sure if I can or should trust' to 'I do not trust' to 'I do not know or have not thought about it'. Finally, respondents were asked to indicate which of three answer options best represented their thoughts on the potential role of the government in reviewing and rating health apps.

<sup>&</sup>lt;sup>26</sup> https://www.researchgate.net/publication/364881170\_25\_The\_immigrant\_minority\_languages\_of\_Europe

## 3.3 Analysis

Only fully completed surveys were analyzed. Descriptive statistics were used to summarize the data (Mean and SD or frequencies and percentages). The final thoughts and comments were translated using DeepL. Thematic analysis was used to identify themes within these thoughts and comments<sup>27</sup>.

 $<sup>^{27}\</sup> https://www.tandfonline.com/doi/abs/10.1191/1478088706qp063oa$ 

## 4 Results

## 4.1 Respondent characteristics

In total 1228 respondents from 33 countries (Appendix 3) completed the survey, making all countries in our scope except Liechtenstein represented by at least 1 respondent. Most respondents, one-third, were from the Netherlands (403, 32.8%), followed by Germany (94, 7.7%,), Belgium (84, 6.8%), Malta (73, 5.9%), Croatia (68, 5.5%), Lithuania (56, 4.6%) and Bulgaria (45, 3.7%). The smallest number of respondents were from Iceland (1, 0.1%), and Hungary (1, 0.1%).

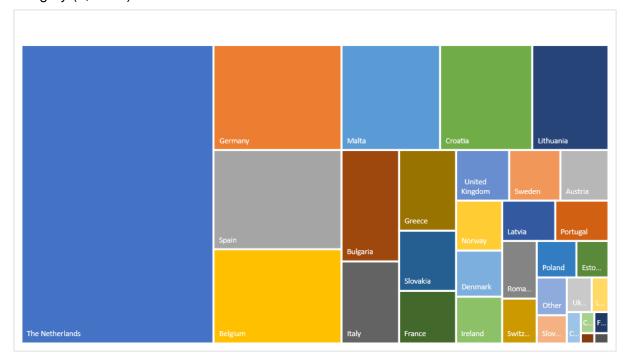


Figure 1. Country of residence of respondents

The respondents had a mean age of 47.0 years (SD 14.8) and two-thirds were female (64.1%). Most were highly educated (bachelor, master, PhD or higher) (81.5%), and had good (48.2%), or very good self-reported health (21.5%). One in four (24.1%) reported having fair health and only 6.2% had poor health. One in three respondents reported providing informal care, with frequencies ranging from every day (8.6%), at least once a week (6.4%) to not every week (10.9%) (Table 1).

| Respondent characteristics |           | (n=1228)     |
|----------------------------|-----------|--------------|
| Age (years), n (%)         |           |              |
|                            | Mean (SD) | 47.0 (14.8)  |
|                            | 65+       | 178 (14.5%)  |
|                            | 18-65     | 1050 (85.5%) |
| Gender, n (%)              |           |              |
|                            | Male      | 438 (35.7%)  |

| Female                                       | 787 (64.1%)  |
|--|--------------|
| Other  | 3 (0.2%)     |
| Education level, n (%)                       |              |
| High school or less                          | 121 (9.9%)   |
| Practical/ vocational education              | 106 (8.6%)   |
| Bachelor/ Master/ Doctor or similar          | 1001 (81.5%) |
| Health status, n (%)                         |              |
| Poor   | 76 (6.2%)    |
| Fair   | 206 (24.1%)  |
| Good   | 592 (48.2%)  |
| Very Good                                    | 264 (21.5%)  |
| Informal care, n (%)                         |              |
| I provide informal care every day            | 106 (8.6%)   |
| I provide informal care at least once a week | 78 (6.4%)    |
| I provide informal care but not every week   | 134 (10.9%)  |
| I do not provide informal care               | 910 (74.1%)  |

**Table 1.** Respondent characteristics

## 4.2 Used health apps

Nine in ten respondents (90.4%) reported using or having used health apps. More than half use or have used COVID-19 (62.1%) or activity apps (60.0%). Almost one in three use or have used health insurance apps or hospital or clinic apps and one in four to five nutrition apps, personal health apps, sleep apps and menstruation apps. The least used apps were informal care apps (1.5%). Disease-related apps such as disease management apps (7.0%), diagnostic apps (6.3%), and treatment apps (5.7%) were reported scarcely too. Female respondents used more often than male respondents nutrition apps (29.1% versus 15.3%) and mindfulness apps (18% versus 9.6%) (Table 2).

|                      |             | Gender         |                |
|----------------------|-------------|----------------|----------------|
|                      |             | Male           | Female         |
| Used apps, n (%)     | Yes         | (n=438, 35.7%) | (n=787, 64.1%) |
| COVID-19 app         | 763 (62.1%) | 287 (65.5%)    | 473 (60.1%)    |
| Activity app         | 737 (60.0%) | 245 (55.9%)    | 491 (62.4%)    |
| Health insurance app | 446 (36.3%) | 174 (39.7%)    | 271 (34.4%)    |

| Hospital or clinic app     | 417 (34.0%) | 129 (29.5%) | 287 (36.5%) |
|----------------------------|-------------|-------------|-------------|
| Nutrition app              | 297 (24.2%) | 67 (15.3%)  | 229 (29.1%  |
| Personal health record app | 271 (22.1%) | 97 (22.1%)  | 174 (22.1%) |
| Sleep app                  | 270 (22.0%) | 96 (21.9%)  | 174 (22.1%) |
| Menstruation app           | 265 (21.6%) | 3 (0.7%)    | 259 (32.9%) |
| Vital signs app            | 217 (17.7%) | 91 (20.8%)  | 126 (16.0%) |
| Mindfulness app            | 186 (15.1%) | 42 (9.6%)   | 142 (18.0%) |
| Disease management app     | 86 (7.0%)   | 32 (7.3%)   | 54 (6.9%)   |
| Diagnostic app             | 77 (6.3%)   | 40 (9.1%)   | 37 (4.7%)   |
| Treatment app              | 70 (5.7%)   | 23 (5.3%)   | 47 (6.0%)   |
| Research app               | 68 (5.5%)   | 23 (5.3%)   | 45 (5.7)    |
| Informal caregiver app     | 19 (1.5%)   | 4 (0.9%)    | 15 (1.9%)   |
| Other                      | 68 (5.5%)   | 18 (4.1%)   | 50 (6.4%)   |
| I don't use a health app   | 118 (9.6%)  | 52 (11.9%)  | 66 (8.4%)   |

Table 2. Which type of health apps do you use or have you used in the past?

## 4.3 Used advice

One in three respondents (35.3%) had used advice from family or friends, a health professional (33.6%) or a government or health authority (29.2%). Less than one in four used advice from app stores (23.7%), a Google search (23.0%) or a health professional organization (247, 20.1%). Few respondents had used advice from a health app manufacturer (8.9%), pharmacist (7.9%) and health app library (5.9%) (Table 3).

|                                    |             | Age         |            |
|------------------------------------|-------------|-------------|------------|
| Used advice - n (%)                | Yes         | <65 years   | >65 years  |
| My family/friends                  | 434 (35.3%) | 400 (38.1%) | 34 (19.1%) |
| A health professional              | 412 (33.6%) | 341 (32.5%) | 71 (39.9%) |
| A government or health authority   | 358 (29.2%) | 327 (31.3%) | 31 (17.4%) |
| App stores                         | 291 (23.7%) | 274 (26.1%) | 17 (9.6%)  |
| A Google search                    | 282 (23.0%) | 257 (24.5%) | 25 (14.0%) |
| A health professional organization | 247 (20.1%) | 210 (20.0%) | 37 (20.8%) |
| Personal social media posts        | 183 (14.9%) | 176 (16.8%) | 7 (3.9%)   |

| A patient organization    | 163 (13.3%) | 131 (12.5%) | 32 (18.0%) |
|---------------------------|-------------|-------------|------------|
| Traditional media         | 155 (12.6%) | 138 (13.1%) | 17 (9.6%)  |
| A peer support group      | 129 (10.5%) | 106 (10.1%) | 23 (12.9%) |
| A health app manufacturer | 109 (8.9%)  | 102 (9.7%)  | 7 (3.9%)   |
| A pharmacist              | 97 (7.9%)   | 78 (7.4%)   | 19 (10.7%) |
| A health app library      | 72 (5.9%)   | 68 (6.5%)   | 4 (2.2%)   |
| None of the above         | 88 (7.2%)   | 73 (7.0%)   | 15 (8.4%)  |
| Other                     | 54 (4.4%)   | 42 (4.0%)   | 12 (6.7%)  |

**Table 3.** Whose advice/tips have you used in the past to choose a health app?

When we stratified by age, we observed that 38.1% of the respondents aged under 65 years old had used advice from family and friends compared to only 19.1% of the respondents aged 65 years and older. On the opposite side, 39.9% of the respondents aged 65 years and older had used advice from health professionals compared to 32.5% of those aged under 65 years old. Respondents in the younger age group (under 65 years) also used more advice from a government or health authority (31.3% versus 17.4%), app stores (26.1% versus 9.6%), a Google search (24.5% versus 14.0%) and personal social media posts (16.8% versus 3.9%) than the older respondents (65 years and older).

### 4.4 Trusted advice

The survey results showed that health professional advice was most trusted (80.4%), followed by pharmacists (61.1%) and government or health authority (59.9%), health professional organizations (56.0%) and family and friends (41.7%). Trust levels for personal social media posts (5.3%), health app manufacturers (9.2%), Google search (9.6%) and app stores (11.7%) were low (Appendix 4).

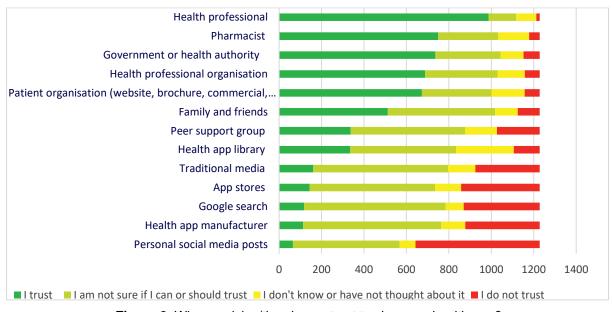


Figure 2. Whose advice/tips do you trust to choose a health app?

We further stratified respondents by education level to explore whether respondents coming from different educational backgrounds trust different sources. We found that people from different educational levels all trust health professionals most, yet trust levels of Bachelor', master, PhD or similar respondents were generally higher, especially for government or health authorities (Table 4).

|                                  |         | Age     |         | Education level            |                               |   |  |
|----------------------------------|---------|---------|---------|----------------------------|-------------------------------|---|--|
| Trusted advice, n (%)            | I trust | <65     | >65     | High<br>school<br>and less | Practical /<br>vocationa<br>I | Bachelor<br>Master<br>PhD or<br>similar |  |
| Health professional              | 987     | 853     | 134     | 90                         | 84                            | 813                                     |  |
|                                  | (80.4%) | (81.2%) | (75.3%) | (74.4%)                    | (79.2%)                       | (81.2%)                                 |  |
| Pharmacist                       | 750     | 648     | 102     | 74                         | 55                            | 621                                     |  |
|                                  | (61.1%) | (61.7%) | (57.3%) | (61.2%)                    | (51.9%)                       | (62.0%)                                 |  |
| Government or health authority   | 736     | 646     | 90      | 64                         | 48                            | 624                                     |  |
|                                  | (59.9%) | (61.5%) | (50.6%) | (52.9%)                    | (45.3%)                       | (62.3%)                                 |  |
| Health professional organization | 688     | 602     | 86      | 55                         | 53                            | 580                                     |  |
|                                  | (56.0%) | (57.3%) | (48.3%) | (45.5%)                    | (50.0%)                       | (57.9%)                                 |  |
| Patient organization             | 673     | 571     | 102     | 62                         | 58                            | 553                                     |  |
|                                  | (54.8%) | (54.4%) | (57.3%) | (51.2%)                    | (54.7%)                       | (55.2%)                                 |  |
| Family and friends               | 512     | 463     | 49      | 50                         | 31                            | 431                                     |  |
|                                  | (41.7%) | (44.1%) | (27.5%) | (41.3%)                    | (29.2%)                       | (43.1%)                                 |  |
| Peer support group               | 337     | 289     | 48      | 41                         | 30                            | 266                                     |  |
|                                  | (27.4%) | (27.5%) | (27.0%) | (33.9%)                    | (28.3%)                       | (26.6%)                                 |  |
| Health app library               | 335     | 301     | 34      | 29                         | 22                            | 284                                     |  |
|                                  | (27.3%) | (28.7%) | (19.1%) | (24.0%)                    | (20.8%)                       | (28.4%)                                 |  |
| Traditional media                | 161     | 136     | 25      | 19                         | 9                             | 133                                     |  |
|                                  | (13.1%) | (13.0%) | (14.0%) | (15.7%)                    | (8.5%)                        | (13.3%)                                 |  |
| App stores                       | 144     | 130     | 14      | 9                          | 12                            | 123                                     |  |
|                                  | (11.7%) | (124%)  | (7.9%)  | (7.4%)                     | (11.3%)                       | (12.3%)                                 |  |
| Google search                    | 118     | 108     | 10      | 11                         | 5                             | 102                                     |  |
|                                  | (9.6%)  | (10.3%) | (5.6%)  | (9.1%)                     | (4.7%)                        | (10.2%)                                 |  |
| Health app manufacturer          | 113     | 104     | 9       | 10                         | 5                             | 98                                      |  |
|                                  | (9.2%)  | (9.9%)  | (5.1%)  | (8.3%)                     | (4.7%)                        | (9.8%)                                  |  |
| Personal social media posts      | 65      | 54      | 11      | 7                          | 4                             | 54                                      |  |
|                                  | (5.3%)  | (5.1%)  | (6.2%)  | (5.8%)                     | (3.8%)                        | (5.4%)                                  |  |

Table 4. Would you trust advice/tips for a health app from ..

#### 4.5 Review and rate

In total 86.3% of the respondents thought the government should review and rate health app quality (54.1%) or pay another organization to do so (32.2%). The remaining 13.7% opted for: 'No, I think the government should not review and rate health app quality and should not pay another organization to review and rate health app quality' (Table 5).

| Review and rate, n (%)   |             |
|--|-------------|
| Yes, I think the government should review and rate health app quality  | 664 (54.1%) |
| No, but I think the government should pay another organization to review and rate health app quality   | 396 (32.2%) |
| No, I think the government should not review and rate health app quality and should not pay another organization to review and rate health app quality | 168 (13.7%) |

**Table 5.** Do you think the government should review and rate health app quality?

## 4.6 Thoughts and comments

In total 211 respondents (17.2%) added final thoughts and comments, and 197 were thoughts and comments on the subject of the survey. We identified three themes. The first theme was apps being a (useful) part of health care: "the future of chronic disease management". "[Apps] should be prescribed and paid for to ensure their continuous improvement" and "to make them accessible to all patients". "Health professionals should think about how they can better utilize data and applications to improve their work." Several gave examples of useful apps, others their limitations; mostly not being able to replace health care professionals: "For example, we can fly a plane in an app but not for that reason do without the pilots. The apps must be supplements for monitoring or clarifying doubts, never replace the criteria of trained personnel." Some disqualified apps altogether: "I really will not work/play with health apps!", "Health is too important to be guided by an app".

A second theme concerned the need for assessment "preferably harmonized throughout Europe" and "at all times apps that authorities initiate themselves": "There are so many health apps that you can no longer see the wood for the trees." "I feel there are many sub-par and uncertified apps (that should be certified) available on various app stores." "How can you pick out the good ones? And trust that they will not misuse your data?" "If you want something to work, you have to evaluate it." "I think it is important that a label is linked to a health app. This way you can clearly see whether the health app is reliable and of good quality." Others suggested a "library of approved health apps". Some referred to their own role: "I would accept every recommendation first and then research the app myself (who is the publisher etc.) and test it." "I test everything myself anyway to see if it fits ME." Two respondents saw no need for an assessment: "Bad apps (such as ovulation mapping to identify safe periods for intercourse) eventually phase themselves out as they increasingly turn out to be bogus." "The quality of the health apps can easily be assessed by health care professionals. I think it's a waste of money to put a lot of effort into this." Others narrowed down the apps that needed to be assessed, for instance, if "it can really affect your health", "they are reimbursed", "are to be used in health care", as "I don't think it's feasible to test all health apps. So many are being launched."

A third theme concerned views on who should review and rate what. Many expressed assessors should be "independent" "with high ethical standards" "no interest in the app and a great deal of knowledge of both the subject and ICT and privacy." Suggestions included: "like a research institute without commercial interests and a high degree of transparency", "health professionals with digital literacy and high quality of health literacy", "an independent advisory board made up of the different stakeholders and a larger group of patients for whom the app is designed". Others had trouble identifying a trusted source: "After the COVID-19 fiasco, I barely trust anyone anymore", and expressed doubts as to the government: "The government should check, but given how it handles sensitive data, I have little confidence in that either" "I don't think government authorities possess a deep-enough understanding, are responsive enough" or "very good at doing things efficiently", "I would rather have the government issue a set of rules", or left it "up to each state", stressing "not temporary financing". With regard to what should be reviewed and rated, see Appendix 5.

One comment summarized the three themes in one sentence: "Trust in health apps comes from certifications, scientific evidence and the authorities' approval and implementation".

## 5 Discussion

## 5.1 Used health apps.

We asked about using health apps for two reasons. One, to ensure the respondents had an adequate understanding of the range of health apps and, two, to get an understanding of the health app usage experience adding perspective to the other responses. Nine in ten used health apps, up from previous research and showing the respondents' level of experience with health apps. COVID-19 and activity apps were the health apps most respondents used. Although some considered uptake of especially COVID-19 tracing apps a failure<sup>28</sup>, these results confirm that COVID-19 has been a blessing for health app uptake, although use is still skewed towards wellness, primarily activity, apps<sup>29,30</sup>.

#### 5.2 Used and trusted advice

In this study, we intentionally asked two related yet distinct questions with regard to recommendations. The first was whose advice people use(d) to choose health apps and the second was whose advice/tips they trusted. As expected, we observed that the respondents trusted advice/tips from health professionals the most, yet their use was considerably less. This seems to prompt further support actions, which as both Australian and European research, the Standing Committee of European Doctors' response to the draft European Health Data Space Regulation and the comments in this survey suggest includes use of (ISO) standards and certification<sup>31,32,33,34</sup>. Equally as expected, family and friends and app stores' advice were used considerably more often than their trust levels suggested. A possible solution previously suggested is requiring app stores to display a health app label showing the performance of the app using standardized scales<sup>35</sup>.

Most respondents indicated that they were not sure whether they could or should trust health app libraries. App libraries were also the least used. Respondents may not know what a health app library is and where to find it. A recent study also saw that in a sample of 18 UK-based adults nobody was aware of the existence of curated portals. The concept was found appealing; however, the reality did not yet meet their needs and expectations<sup>36</sup>. Around the same time, the NHS decided to close their NHS Library and instead link to recommended apps throughout their likely already widely used and trusted NHS website<sup>37</sup>. France uses their national portal Mon Espace Santé<sup>38</sup>, while Norway has reviewed 5 wellness apps and added 2 to their national portal for easy access<sup>39</sup>. The German DiGA Directory is a separate app library. According to the insurer Techniker Krankenkasse (TK), only 4 percent of physicians had prescribed a DiGA as of early 2022. Promising is that two in three (63%) of the patients

<sup>&</sup>lt;sup>28</sup> https://cepr.org/voxeu/columns/economic-incentives-and-regulation-increase-covid-19-app-effectiveness

<sup>29</sup> https://www.iqvia.com/newsroom/2021/07/consumer-health-apps-and-digital-health-tools-proliferate-improving-quality-and-health-outcomes-for

<sup>30</sup> https://www.businessillustrator.com/what-is-digital-transformation-cartoon-infographic/

<sup>31</sup> https://pubmed.ncbi.nlm.nih.gov/31199343/Byambasuren et al (2019) Current knowledge and adoption of mobile health apps among Australian General Practitioners: Survey study

<sup>32</sup> https://mhealth.jmir.org/2022/2/e28372

<sup>33</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7974757/

<sup>34</sup> https://www.cpme.eu/api/documents/adopted/2022/11/cpme.2022-065.FINAL.CPME.position.EHDS.pdf

<sup>35</sup> https://jamanetwork.com/journals/jama/article-abstract/2707668

<sup>36</sup> https://mhealth.jmir.org/2021/4/e27173

<sup>37</sup> https://www.nhs.uk/apps-library/

<sup>38</sup> https://www.ameli.fr/assure/actualites/mon-espace-sante-s-enrichit-d-un-catalogue-de-services

<sup>&</sup>lt;sup>39</sup> https://www.helsedirektoratet.no/om-oss/forsoksordninger-og-prosjekter/tryggere-helseapper

who have used a DiGA report a positive clinical outcome, and 86% would use another DiGA to treat or manage a future medical condition<sup>40</sup>.

Of further interest in our survey is the high level of trust in pharmacists' advice, which is currently scarcely used.—It signals that pharmacists could potentially play a role in recommending or offering advice about health apps, as previously suggested<sup>41</sup>, reducing health professionals' concerns with regard to demands on their time helping patients get started<sup>42,43</sup>.

#### 5.3 Review and rate

Similar to the previously mentioned Australian study<sup>44</sup>, nearly nine in ten respondents thought the government should review and rate health app quality or pay somebody else to do it. Increasingly, governments launch their own app assessment frameworks. Yet as the mHealth Hub study showed, most countries in Europe still lack a framework<sup>45</sup>. Research of 9 countries' policies including 7 European ones found even the front runners lack efficiency, advocating for more cross-national efforts<sup>46</sup>. The European Health Data Space Draft Regulation proposes labelling of wellness apps "and a cascading effect in medical devices". Draft Article 31 requires each supplier for which a label has been issued to ensure that each app that is placed on the market or put into service is accompanied by the label free of charge and each distributor of an application to make the label available to customers at the point of sale.

## 5.4 Thoughts and comments

Labelling of apps (Article 31 of the draft European Health Data Space Regulation) was not referred to in the survey and the CEN-ISO 82304-2 label was not displayed, yet several respondents expressed a need for harmonized assessment and suggested a label or quality mark. "Trust in health apps comes from certifications, scientific evidence and the authorities' approval and implementation." The respondents' comments on app requirements, including scientific evidence, mirrored the 82304-2 assessment framework and label. See Appendix 5.

## 5.5 Strengths and limitations

It is important to note some strengths and limitations:

• One of the strengths of this study is its inclusive design. Being simple, short, in lay language and available in 26 languages made the survey accessible to a wide range of respondents, also to those who do not regularly engage in research. This resulted in a response rate of 1228 persons including 9.9 % of persons with high school education or less and 14.5% aged 65 or older and, although skewed towards

<sup>&</sup>lt;sup>40</sup> https://www.mckinsey.com/industries/life-sciences/our-insights/german-e-health-offerings-expand-but-adoption-remains-uneven

<sup>41</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6997363/

<sup>42</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7974757/

<sup>43</sup> https://link.springer.com/article/10.1007/s10354-021-00814-0

https://chf.org.au/sites/default/files/results\_of\_australias\_health\_panel\_survey\_on\_recommendations\_and\_regul ation\_of\_smartphone\_apps\_for\_health\_and\_wellness.pdf

<sup>45</sup> https://mhealth-hub.org/assessment-frameworks

<sup>46</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8933556/

some countries, responses from all 34 targeted European countries except Liechtenstein.

- To achieve a response throughout Europe we used a digital survey. Individuals who
  voluntarily participate in digital surveys may differ from those who do not, resulting
  in a sample that is not fully representative of the target population.
- Despite the large number of respondents in this study, the survey results have not been analyzed for margin of error or statistical significance. As such the findings may be more indicative of broader themes rather than conclusive.

## 6 Conclusions

Our survey results show that 86.3% of European residents thought their government (or health authority) should rate and review health apps or commission a third-party to do so, urging governments to pursue such efforts to help address the challenges their health systems face, preferably in cross-country harmonized efforts. Recommendations for health apps from trusted sources were underutilized, while untrusted sources were used, signaling a need for trusted information in untrusted sources, such as display of the CEN-ISO/TS health app quality score, label and report, and support measures to promote recommendations for health apps by trusted sources (health professionals, pharmacists). This trusted information and support measures include, and as such refer back to, having trusted health app assessments easily available.

The Label2Enable project will use the findings of this survey to co-create and test educational communication on the CEN-ISO/TS 82304-2 health app quality label and to engage in patient advocacy. Other project tasks include addressing health professionals' needs by creating guidance on the level of detail in the CEN-ISO/TS 82304-2 health app quality report that enables health professionals to confidently recommend apps. And a study on how to display the label in app stores, app libraries and trusted sources (e.g., government or health care professional organization websites). Further research is recommended to explore the potential role of the pharmacist in the uptake of trusted health apps and in general effective support measures to promote health app assessments.

The Label2Enable Coordination and Support Action (Jun22-May24) is a Horizon Europe project that aims to promote the Europe-wide adoption of CEN-ISO/TS 82304-2 and its quality label for health and wellness apps. The project has 3 pillars: Trust, Use and Adoption of a quality certification scheme. The main deliverable of the Trust pillar is a robustly tested, efficient, self-explanatory certification scheme for the CEN-ISO 82304-2 health app assessment framework, that (a) complies with the ISO 17000 certification series and all applicable EU-level legislation and core values, (b) is easy to use for (accredited) app assessors and app manufacturers, (c) is trusted by end users, health care professionals (HCPs) and insurers, and (d) delivers consistent results. The main deliverable of the Use pillar is information and communication materials to support residents in downloading and using an app and HCPs in recommending an app. The main aim of the Adoption pillar is a single market (cross-country recognition of 82304-2's certification scheme). The Label2Enable consortium partners mirror the main mHealth stakeholders. Leiden University Medical Center coordinates the Label2Enable project

## 7 Appendix 1: Study survey

| Question  | Response options   |
|-----------|--------------------|
| 440011011 | Trooperior options |

#### Section 1: Respondent characteristics

The first six questions help to assess if the respondents of this survey are as diverse as the European population.

The answers may also help work out how to best address the needs and preferences of subgroups.

| 1 | In which country do you live (primarily)?   | Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, Ukraine, Other |  |  |
|---|---|---|--|--|
| 2 | What year were you born?  | Drop down menu of 1900 to 2005  |  |  |
| 3 | What is your gender?  | <ul><li>Male</li><li>Female</li><li>Other</li></ul>   |  |  |
| 4 | What is your education level?   | <ul> <li>Elementary school or less</li> <li>High school</li> <li>Practical/ vocational education</li> <li>Bachelor/ Master/ Doctor or similar</li> </ul>  |  |  |
| 5 | In general, would you say your health is  | <ul><li>Poor</li><li>Fair</li><li>Good</li><li>Very good</li></ul>  |  |  |
| 6 | Do you provide informal care? (Informal care is care for a chronically ill, disabled, or elderly family member or friend) | <ul> <li>Yes, I provide informal care every day</li> <li>Yes, I provide informal care at least once a week</li> <li>Yes, I provide informal care but not every week</li> <li>No, I do not provide informal care</li> </ul>  |  |  |

#### Section 2: Use

Combined with the first questions this next question tells who uses which type of health apps (already).

| <ul> <li>Nutrition app (apps to track what you eat, your body weight, etc.)</li> <li>Sleep app (apps to track your sleep)</li> </ul> |
|--|
|--|

- Menstruation app (apps to track and predict your period, your most fertile days, etc.)
- Mindfulness app
- Vital signs app (apps to track your blood pressure, heart rate, body temperature, breathing rate)
- Disease management apps (apps to learn more about your disease, apps to help take your medication in time, apps to track your symptoms, etc., for example, diabetes apps, cancer apps, heart disease apps)
- Informal caregiver app (apps to help a chronically ill, disabled, or elderly family member or friend with their health and care)
- Research apps (apps to participate in medical research)
- Diagnostic app (apps to assist in diagnosing a medical condition, for example, checking your skin to detect cancer, measuring your heart rate to detect a heart condition, etc.)
- Treatment apps (physiotherapy apps, rehabilitation apps, apps to treat mental conditions such as depression, etc.)
- Other, Please mention which other health apps you use.
- I don't use a health app

#### **Section 3: Trust**

The next two questions explore whose recommendations you use and trust in choosing health apps.

Your answers indicate who can help distribute information materials about choosing health apps.

| Tour answers indicate who can help distribute information materials about choosing health apps. |   |  |  |  |
|---|---|--|--|--|
| 8   | Whose advice/tips have you used in the past to choose a health app? (more than one answer possible) | <ul> <li>A health professional (medical doctor, nurse, physiotherapist, etc.)</li> <li>A pharmacist</li> <li>A health app library</li> <li>A government or health authority (website, brochure, commercial, etc.)</li> <li>A health professional organization (website, brochure, commercial, etc.)</li> <li>A patient organization (website, brochure, commercial etc.)</li> <li>A peer support group (for example Facebook group for patients with a specific health issue)</li> <li>My family/friends</li> <li>Traditional media (newspapers, magazines, radio, television)</li> <li>Personal social media posts (Facebook, Instagram, etc., including influencers)</li> <li>The App Store or Google Play store (includes manufacturer information, user reviews, and order the apps are displayed)</li> <li>A Google search</li> <li>A health app manufacturer (includes advertisements)</li> <li>Other, Please mention whose other advice/tips you used</li> <li>None of the above</li> </ul> |  |  |
| 9   | Would you trust advice/tips for a health app from   | <ul> <li>I trust</li> <li>I am not sure if I can or should trust</li> <li>I do not know or have not thought about it</li> <li>I do not trust</li> </ul>  |  |  |
|   |   |  |  |  |

- A health professional (medical doctor, nurse, physiotherapist, etc.)?
- A pharmacist?
- A health app library
- A government or health authority (website, brochure, commercial, etc.)
- A health professional organization (website, brochure, commercial, etc.)
- A patient organization (website, brochure, commercial etc.)
- A peer support group (for example Facebook group for patients with a specific health issue)
- My family/friends
- Traditional media (newspapers, magazines, radio, television)
- Personal social media posts (Facebook, Instagram, etc., including influencers)
- The App Store or Google Play store (Includes manufacturer information, user reviews, and order the apps are displayed)
- A Google search
- A health app manufacturer (includes advertisements)
- Other, Please mention whose other advice/tips you use
- None of the above

#### Section 4: Review and rate

Some European governments have adopted a method to review and rate health apps, others have not. Your answer helps Label2Enable address thoughts on reviewing and rating health apps with governments. If you have anything further to add then please detail your thoughts and comments in the last question.

Do you think the government should review and rate health app quality to help you choose a health app?

10 (Government includes health authorities such as the Ministry of Health.

Health app quality includes if the app benefits health, is safe, easy

- Yes, I think the government should review and rate health app quality
- No, but I think the government should pay another organization to review and rate health app quality
- No, I think the government should not review and rate health app quality and should not pay another organization to review and rate health app quality

|    | to use, reliable, secures data, etc.)                 |  |
|----|---|--|
| 11 | Any final thoughts or comments you would like to add? |  |

Thank you for your participation.

You can find the results of this survey in early 2023 on the Label2Enable website (www.label2enable.eu).

Table 6. Survey

# 8 Appendix 2: Screenshot survey on the website



Figure 3. Screenshot survey on the website

# 9 Appendix 3: Countries of residence of respondents

| Country         | n (%)       |
|-----------------|-------------|
| The Netherlands | 403 (32.8%) |
| Germany         | 94 (7.7%)   |
| Spain           | 89 (7.2%)   |
| Belgium         | 84 (6.8%)   |
| Malta           | 73 (5.9%)   |
| Croatia         | 68 (5.5%)   |
| Lithuania       | 56 (4.6%)   |
| Bulgaria        | 45 (3.7%)   |
| Italy           | 33 (2.7%)   |
| Greece          | 32 (2.6%)   |
| Slovakia        | 24 (2.0%)   |
| France          | 21 (1.7%)   |
| United Kingdom  | 19 (1.5%)   |
| Sweden          | 18 (1.5%)   |
| Austria         | 17 (1.4%)   |
| Norway          | 16 (1.3%)   |
| Denmark         | 15 (1.2%)   |
| Ireland         | 15 (1.2%)   |
| Latvia          | 15 (1.2%)   |
| Portugal        | 15 (1.2%)   |
| Romania         | 14 (1.1%)   |
| Switzerland     | 11 (0.9%)   |
| Poland          | 10 (0.8%)   |
| Estonia         | 8 (0.7%)    |
| Other           | 8 (0.7%)    |

| Slovenia      | 6 (0.5%)    |
|---------------|-------------|
| Ukraine       | 6 (0.5%)    |
| Luxembourg    | 4 (0.3%)    |
| Cyprus        | 3 (0.2%)    |
| Czechia       | 2 (0.2%)    |
| Finland       | 2 (0.2%)    |
| Hungary       | 1 (0.1%)    |
| Iceland       | 1 (0.1%)    |
| Liechtenstein | 0 (0.0%)    |
| Total         | 1228 (100%) |

Table 7. Country of residence of respondents

# 10 Appendix 4: Trusted advice

| Trust  | l trust<br>n (%) | I am not sure if<br>I can or should<br>trust<br>n (%) | I do not know<br>or have not<br>thought about it<br>n (%) | I do not trust<br>n (%) |
|--|------------------|---|---|-------------------------|
| Health professional  | 987 (80.4%)      | 130 (10.6%)   | 95 (7.7%)   | 16 (1.3%)               |
| Pharmacist   | 750 (61.1%)      | 283 (23.0%)   | 145 (11.8%)   | 50 (4.1%)               |
| Government or health authority                             | 736 (59.9%)      | 307 (25.0%)   | 109 (8.9%)  | 76 (6.2%)               |
| Health professional organization                           | 688 (56.0%)      | 342 (27.9%)   | 128 (10.4%)   | 70 (5.7%)               |
| Patient organisation (website, brochure, commercial, etc.) | 673 (54.8%)      | 328 (26.7%)   | 156 (12.7%)   | 71 (5.8%)               |
| Family and friends   | 512 (41.7%)      | 506 (41.2%)   | 107 (8.7%)  | 103 (8.4%)              |
| Peer support group   | 337 (27.4%)      | 540 (44.0%)   | 150 (12.2%)   | 201 (16.4%)             |
| Health app library   | 335 (27.3%)      | 499 (40.6%)   | 272 (22.1%)   | 122 (9.9%)              |
| Traditional media  | 161 (13.1%)      | 635 (51.7%)   | 129 (10.5%)   | 303 (24.7%)             |
| App stores   | 144 (11.7%)      | 591 (48.1%)   | 123 (10.0%)   | 370 (30.1%)             |
| Google search  | 118 (9.6%)       | 667 (54.3%)   | 85 (6.9%)   | 358 (29.2%)             |
| Health app manufacturer                                    | 113 (9.2%)       | 651 (53.0%)   | 113 (9.2%)  | 351 (28.6%)             |
| Personal social media posts                                | 65 (5.3%)        | 503 (41.0%)   | 75 (6.1%)   | 585 (47.6%)             |

 $\textbf{Table 8.} \ \ \textbf{Would you trust advice/tips for a health app from } ..$ 

## 11 Appendix 5: Alignment label with comments

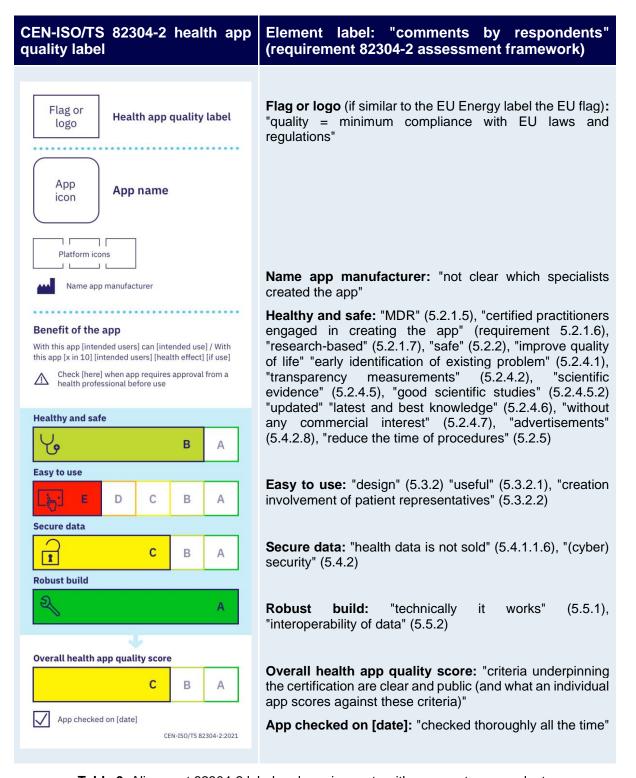


 Table 9. Alignment 82304-2 label and requirements with comments respondents